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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/928,027	08/10/2001	Geert Willem Meijer	F6143	5214

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UNILEVER
PATENT DEPARTMENT
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EXAMINER
SNEDDEN, SHERIDAN

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 03/26/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/928,027	MEIJER ET AL.	
	Examiner	Art Unit	
	Sheridan K Snedden	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-29 is/are pending in the application.

4a) Of the above claim(s) none is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-29 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7,8,9 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16-26 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 recites the limitation "one or more foods" with reference to claim 1. There is insufficient antecedent basis for this limitation in the claim.

Claims 16-26 recite the limitation "calcium" in reference to the composition of claim 1. However, calcium is not recited in the composition of claim 1. There is insufficient antecedent basis for this limitation in the claim. Applicant may overcome this rejection by including language suggesting the further addition of calcium to the composition.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-14 and 20-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Hahn (US 6,241,996). Hahn teaches nutritional dietary composition that can be formulated for oral administration. The composition is a high soy protein-containing formulation that is naturally high in isoflavones and phytosterols that have been associated with positive nutritional effects such as the reduction of blood serum cholesterol levels (see column 4, lines 5-11; regarding claims 2 and 12). Beta-sitosterol is a soybean phytosterol and genistein and daidzein are soybean isoflavones naturally present in the above formulation (regarding claims 3 and 4).

Hahn teaches the above composition as a daily dietary supplement that has the additional advantage of lowering blood cholesterol levels, due to the presence of isoflavones and phytosterols naturally present in soy (see column 3, lines 23-55 and column 4, lines 5-11). Administration of the above composition includes the step of feeding the above composition to a human patient (regarding claims 1, 11, 13). The process of consuming the above composition as a dietary supplement would inherently result in the reduction of cholesterol in the patient and the process would be identical to the claimed invention as both the reference process and the claimed process involved the step of feeding an identical composition to a human. As the soy-based formulation is meant as a dietary supplement, the process inherently includes the serving of additional food servings (regarding claim 14).

The formulation taught by Hahn is optionally made with soy protein concentrate, which contains soy fiber. The soy protein concentrate is added in amounts of from 1.0 wt. % to 5.0 wt. % of the total weight formulation and preferably in an amount of 2.5 wt % to 3.0 wt %, which would equate to a total fiber content of less than 3% (column 5, lines 1-10, column 6, lines 12-15; regarding claims 5-10). A dispersible, non-reactive form of magnesium comprises a third

component of the nutritional soy protein formulation and this prevents soy protein denaturation and/or thickening. Example 5 teaches the above composition additionally containing 0.11% Calcium Caseinate, which would equate to less that 0.1% calcium (regarding claims 20-25). Thus, the reference anticipates the claimed invention.

4. Claims 1-14 and 27-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Waggle *et al.* (US 2001/0024666 A1). Waggle *et al.* teach a composition comprising a sterol and a soy protein material and isoflavone selected from genistein, daidzein, glycitein, biochanin A, formononetin, and their naturally occurring glycosides (see claim 1 and section 0024; regarding claim 2, 3 and 12). Waggle *et al.* also teach a method for decreasing the blood concentration of total and LDL cholesterol in a human in which a sterol, a soy protein material and an isoflavone are co-administered to the human, where the sterol comprises at least 0.49%, by weight, of the combined weight of the plant sterol and the soy protein material and/or the isoflavone (see section 0024; regarding claims 1, 3, 11 and 13). Beta-sitosterol is a soybean phytosterol that would be naturally present in the above formulation (regarding claim 4).

The formulation taught by Waggle is optionally made with soy protein concentrate, which contains soy fiber. Additionally, examples of the above soy-based formulation for use in the process of lowering cholesterol in a patient is taught as optionally containing cellulose (see section 0045 and 0098; regarding claims 5-10). As the soy-based formulation above is meant as a dietary supplement, the process inherently includes the serving of additional food servings (regarding claim 14).

Additionally, the example formulation of section 0072, for use in the process of lowering cholesterol in a patient, teaches the above soy-based formulation as containing 250-500 mg/caplsule of sterol, 0.5-2g/tablet of soy protein, and 25-100 mg/capsule of isoflavone (see section 0072 and page 8; regarding claims 27-29). Thus, the reference anticipates the claimed invention.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-29 rejected under 35 U.S.C. 103(a) as being unpatentable over Waggle *et al.* (US 2001/0024666 A1), in view of Mehansho *et al.* (US 2002/0155194 A1).

Waggle *et al.* teach a composition comprising a sterol and a soy protein material and isoflavone selected from genistein, daidzein, glycitein, biochanin A, formononetin, and their naturally occurring glycosides (see claim 1 and section 0024; regarding claim 2, 3 and 12). Waggle *et al.* also teach a method for decreasing the blood concentration of total and LDL cholesterol in a human in which a sterol, a soy protein material and an isoflavone are co-administered to the human, where the sterol comprises at least 0.49%, by weight, of the combined weight of the plant sterol and the soy protein material and/or the isoflavone (see section 0024; regarding claims 1, 3, 11 and 13). Beta-sitosterol is a soybean phytosterol that

would be naturally present in the above formulation (regarding claim 4). The formulation taught by Waggle is optionally made with soy protein concentrate, which contains soy fiber.

Additionally, examples of the above soy-based formulation for use in the process of lowering cholesterol in a patient is taught as optionally containing cellulose (see section 0045 and 0098; regarding claims 5-10). As the soy-based formulation above is meant as a dietary supplement, the process inherently includes the serving of additional food servings (regarding claim 14). Additionally, the example formulation of section 0072, for use in the process of lowering cholesterol in a patient, teaches the above soy-based formulation as containing 250-500 mg/caplsule of sterol, 0.5-2g/tablet of soy protein, and 25-100 mg/capsule of isoflavone (see section 0072 and page 8; regarding claims 27-29). Thus, the reference anticipates the claimed invention.

Waggle *et al.* does not teach the addition of a calcium salt (regarding claims (16-19 and 26).

Mechansho *et al.* teach an ingestible formulations comprising soy protein in the form of, for example, soy protein isolate, soy protein concentrate, and/or soy flour. All of these forms will typically contain isoflavones and phytosterols (see section 0035). Mechansho *et al.* teach that the above formulation would also include vitamins and minerals, such as calcium (see section 0073). Mechansho *et al.* teach that calcium salts, such as calcium chloride, is a preferred source of calcium (see section 0089 and 0090) and that the calcium would be present in an amount from 0 to 5% calcium, preferably between 0.01% - 0.5% (see section 0091, regarding claims 16-26).

Taken together, the above reference teach a soy-based formulation for the purpose of lowering cholesterol in a human comprising soy protein, isoflavones, phytosterols and less than 0.3% calcium, optionally comprising fiber. It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use a calcium salt as a source of calcium for the formulation taught by Waggle *et al.*. The formulations would contain between 0-5% calcium as taught by Mechansho *et al.* A person of ordinary skill in the art would have expected success as each of these ingredient are commonly used in the soy-based formulations taught in the prior art. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (703) 305-4843. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone number for regular communications to the organization where this application or proceeding is assigned is (703) 746-3975.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS
March 24, 2003

SKS

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER